UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

ELMER HEISNER, INDIVIDUALLY AND ON BEHALF OF, JAYNE HEISNER, Plaintiff, vs. GENZYME CORPORATION, a Massachusetts Corporation, Defendant.	Case No: 08 C 593 Judge Coar Magistrate Judge Denlow

AMENDED COMPLAINT

NOW COMES the Plaintiff, ELMER HEISNER, Individually and on behalf of the deceased, JAYNE HEISNER, ("Plaintiff"), by and through his attorneys, THE LAW GROUP, LTD., and complaining of the Defendant, GENZYME CORPORATION, states as follows:

I. PARTIES

A. PLAINTIFF

1. Plaintiff, ELMER HEISNER, is a citizen and resident of the state of Illinois.

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2. The deceased, JAYNE HEISNER, was also a citizen and resident of Illinois. JAYNE HEISNER underwent surgery to remove an ovarian cyst on January 19, 2006. At that time a Seprafilm adhesion barrier was placed into her body to prevent potential postsurgical adhesions. Soon thereafter on February 22, 2006, JAYNE HEISNER died as a proximate result of the implanation of Seprafilm into her body. JAYNE HEISNER is survived by her husband ELMER HEISNER and her adult children: LAURA SCHMITZ, DAVID HEISNER, LINDA MCKIMMY, and CAROL HULSLANDER.

B. DEFENDANT

3. Defendant, GENZYME CORPORATION, is a Massachusetts Corporation with its principal place of business located at 500 Kendall Street, Cambridge, Massachusetts, 02142.

4. GENZYME is a life sciences company, whose core products include enzyme replacement therapy products, adhesion prevention, and other pharmaceutical products, including Seprafilm.

5. At all times relevant hereto, Defendant, GENZYME, was engaged in the business of designing, licensing, manufacturing, selling, marketing, distributing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, a medical device known as Seprafilm.

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II. JURISDICTION

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332 (diversity jurisdiction) because the amount in controversy exceeds $75,000 exclusive of interest and costs, and because this is an action by an individual Plaintiff and Defendant who are each citizens of a different state.

7. GENZYME is a corporation headquartered in and a resident of the State of Massachusetts. Defendant has, therefore, subjected itself to personal jurisdiction and venue is proper in this District pursuant to 28 U.S.C. § 1391.

8. The Plaintiff, ELMER HEISNER, is a citizen and resident of the State of Illinois.

9. The deceased, JAYNE HEISNER, was a citizen and resident of the State of Illinois at the time of her death.

III. FACTUAL ALLEGATIONS

10. Seprafilm, manufactured by GENZYME, is intended to be a device used by medical professionals to prevent adhesions in those undergoing pelvic or laparotomy procedures by separating traumatized tissue surfaces after one undergoes pelvic and/or abdominal surgery. Adhesions are a dangerous condition that if left untreated can cause serious health risks, including death, to patients post surgical procedure.

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11. An adhesion is an internal scar that may form after surgery on or between manipulated internal organs and/or body tissue. Adhesions between tissue can twist and pull organs out of their normal places.

12. Seprafilm Adhesion Barrier was approved by the United States Food and Drug Administration ("FDA") on December 20, 2000.

13. The FDA has published evidence of documented permanent injuries, including death, for those persons who have endured a surgical procedure and were given Seprafilm intended to prevent postoperative adhesions in the body.

14. Merely some of the adverse reactions of Seprafilm published by the FDA include: death, severe chronic inflammation of the small bowel area, small bowel obstruction, concrete abdomen, concrete intestines, adhesion of internal organs, dense fibroids, extremely high fever, severe adhesive intestinal obstruction, and vaginal bleeding.

IV. CLAIMS FOR RELIEF

COUNT 1
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY: 810 ILCS 5/2-314 AND UCC §2-314

15. Plaintiffs reallege and incorporate paragraphs 1-14 of this Complaint.

16. Seprafilm is a "good" as defined in UCC §2-314(2); 810 ILCS 5/2-314.

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17. GENZYME is a "merchant" as defined in UCC §2-314(1); 810 ILCS 5/2-314.

18. To be merchantable, goods must, among other things, at least be fit for the ordinary purposes for which such goods are used.

19. GENZYME's defective Seprafilm was sold with the implied warranty of merchantability, meaning it would (a) pass without objection in the trade; (b) was fit for the ordinary purpose for which is was used; (c) would run of even kind, quality, and quantity within each unit and among all units involved; (d) was adequately contained, labeled, and packaged; and (e) conformed to GENZYME's promises or affirmations of fact made on its container and label.

20. By virtue of its defect, GENZYME's Seprafilm did not (a) pass without objection in the trade, in that it caused and had the propensity to cause concrete intestines; (b) was not fit for its ordinary purpose for which anti-adhesion products are used, in that it caused and had the propensity to cause concrete intestines; (c) did not run of even kind, quality, and quantity within each unit and among all units involved in that it caused and had the propensity to cause concrete intestines; (d) was not adequately contained, labeled, and packaged, in that it caused and had the propensity to cause concrete intestines; and, accordingly (e) did not conform to the promises or affirmation of fact made on its container and label as a product that solely prevents adhesions by separating traumatized

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tissue surfaces, in that it caused and had the propensity to cause concrete intestines.

21. As a proximate result of GENZYME's breach of the implied warranty of merchantability, due to the fact that Seprafilm was a good that was not of merchantable quantity, Plaintiff suffered money damages.

COUNT II
STRICT LIABILITY PURSUANT TO §402A OF THE RESTATEMENT (SECOND) OF TORTS

22. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

23. The Defendant, from its headquarters in Massachusetts, made every and all decisions regarding the manufacturing, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, warning, and otherwise distributing Seprafilm in the United States, which it sold and distributed throughout the United States to the doctors which implanted the device into the Decedent's body.

24. JAYNE HEISNER was using Seprafilm in a manner for which it was intended or in a reasonably foreseeable manner.

25. Seprafilm was expected to and did reach the Plaintiff without substantial change in its condition as manufactured, created, designed, tested,

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labeled, sterilized, packaged, supplied, marketed, sold, advertised, warned, and otherwise distributed.

26. The Plaintiff was not aware of, and reasonably could not have discovered, the dangerous nature of Seprafilm.

27. The Defendant's Seprafilm caused increased risks of concrete intestines, and therefore constitutes a product unreasonably dangerous for normal use due to its defective design, defective manufacture, and the GENZYME's misrepresentations and inadequate facts disclosed to the JAYNE HEISNER.

28. As a direct and proximate result of GENZYME's decision making process, related to the manufacturing, creating, designing, testing, labeling, sterilizing, packaging, supplying, marketing, selling, advertising, warning, and otherwise distributing Seprafilm, JAYNE HEISNER suffered concrete intestines and died and consequently suffered compensatory and punitive damages in an amount to be proven at trial.

29. GENZYME, therefore, is strictly liable to the Plaintiff. Additionally, Defendant's conduct was so outrageous as to constitute ill will, bad motive and reckless indifference to the interests of the consumers. The Plaintiff, therefore, is entitled to punitive damages.

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COUNT III
NEGLIGENCE

30. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

31. It was the duty of the Defendant to use reasonable care in the design, manufacture, marketing, selling, advertising, warning, and otherwise distributing Seprafilm.

32. Contrary to its duty, the Defendant was guilty of one or more of the following careless and negligent acts and/or omissions:

(A). Failed to adequately and properly test and inspect Seprafilm so as to ascertain whether or not it was safe and proper for the purpose for which it was designed, manufactured and sold;

(B). Failed to utilize and/or implement a reasonably safe design in the manufacture of Seprafilm;

(C). Failed to manufacture Seprafilm in a reasonably safe condition for which it was intended;

(D). Failed to adequately and properly warn Plaintiff and Plaintiff's health care provider purchasing Seprafilm of the risks of complications when used in a manner for which it was intended;

(E). Failed to adequately and properly warn Plaintiff and/or Plaintiff's health care provider purchasing Seprafilm of the risks of diseases when used in a manner for which it was intended;

(F). Failed to adequately and properly label Seprafilm so as to warn the Plaintiff of the risks of complications;

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(G). Failed to adequately and properly label Seprafilm so as to warn the Plaintiff of the risks of concrete intestines;

(H). Manufactured Seprafilm which constituted a hazard to health;

(I). Manufactured Seprafilm which caused adverse side effects; and

(J). Were otherwise careless and negligent.

33. As a direct and proximate result of GENZYME's marketing, selling, advertising, and otherwise distributing Seprafilm, Plaintiff is at an increased risk of developing concrete intestines and has suffered compensatory and punitive damages in an amount to be proven at trial.

COUNT IV
NEGLIGENCE PER SE

34. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

35. GENZYME had an obligation not to violate the Premarket Approval Regulations pursuant to the Medical Device Amendments codified at 21 U.S.C. § 360, et seq.; §360(e)(1)(A-D); 21 C.F.R. 801.1; 801.6; 801.109 and 21 C.F.R § 814.39(d)(1) and (2) and the specific August 12, 1996 Seprafilm Premarket Approval (PMA) Order Number P950034 and Supplement Number 027, in the manufacture, design, formulation, compounding, testing, production, processing, assembly, inspection, research, distribution, marketing, labeling, packaging, preparation for use, sale and warning of the risks and dangers of Seprafilm.

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36. Plaintiff, as a purchaser and consumer of Seprafilm, is within the class of persons the statutes and regulations described above are designed to protect and Plaintiff's injury is of the type of harm these statutes are designed to prevent.

37. GENZYME's acts constitute an adulteration and/or misbranding as defined by the Medical Device Amendments codified at 21 U.S.C. § 360. et seq. and the specific Seprafilm PMA P950034 constitutes a breach of duty subjecting GENZYME to civil liability for all damages arising therefrom, under theories of negligence per se.

38. GENZYME failed to meet the standard of care set by the following statutes and regulations, which were intended for the benefit of individuals such as the Plaintiff, making GENZYME negligent per se:

(A) The labeling lacked adequate information on the use of the product Seprafilm [21 C.F.R. Section 801.1; 801.5;

(B) The labeling failed to provide adequate warnings of severe and disabling medical conditions including, without limitations, concrete intestines and other adverse medical conditions as soon as there was reasonable evidence of their association with the product [21 C.F.R. 801.4; 801.5; 801.109; Seprafilm PMA P950034 Supplement Number 027

(C) There was inadequate information for patients and/or health care providers for the safe and effective use of GENZYME's product [21 C.F.R. 801.5; 801.109];

(D) There was inadequate information regarding special care to be exercised by the doctor for safe and effective use of GENZYME's product [21 C.F.R. 801.5; 801.109]; and

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(E) The labeling was misleading and promotional [21 C.F.R. 801.6].

39. As a result of the violations of the statutes described above, Plaintiff suffered injuries and damages as alleged herein.

COUNT V
BREACH OF EXPRESS WARRANTY

40. Plaintiff repeats and realleges, as if fully set forth herein, each and every allegation contained in the above paragraphs and further alleges:

41. GENZYME expressly warranted to Plaintiff, by and through statements made by GENZYME or their authorized agents, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that Seprafilm was safe, effective, fit and proper for its intended use.

42. In using Seprafilm, Plaintiff relied on the skill, judgment, representations and foregoing express warranties of the GENZYME. Said warranties and representations were false in that the aforementioned product was not safe and was unfit for the uses for which it was intended.

43. As a direct and proximate result of GENZYME's breach of warranty, JAYNE HEISNER was at an increased risk of developing concrete intestines and has suffered compensatory and punitive damages in an amount to be proven at trial.

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PRAYER FOR RELIEF

WHEREFORE, Plaintiff, ELMER HEISNER, by and through his attorneys, THE LAW GROUP, LTD., prays for relief as follows:

1. For general damages in a sum in excess of the jurisdictional minimum of this Court;
2. Medical, incidental, hospital and service expenses according to proof;
3. Loss of earnings and earning capacity according to proof;
4. Prejudgment and post judgment interest as provided by law;
5. Compensatory damages in excess of the jurisdictional minimum of the Court, according to proof;
6. Consequential damages in excess of the jurisdictional minimum of the Court, according to proof;
7. Damages for the Wrongful Death of JAYNE HEISER pursuant to the Illinois Wrongful Death Act, 740 ILCS 180/1;
8. Damages awarded pursuant to the State of Illinois Survival Act, 755 ILCS 5/27-6, 740 ILCS 180/2;
9. Damages for loss of consortium and society;
10. Punitive and exemplary damages;
11. Attorneys' fees, expenses and costs of this action; and
12. Such further relief as this Court deems necessary, just and proper.

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DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial on all claims so triable in this action.

RESPECTFULLY SUBMITTED,

By: /s/ Kurt D. Hyzy
Kurt D. Hyzy, #6196871
Pamela G. Sotoodeh, #6284622
Lynn M. Herbstman, #6286390
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CERTIFICATE OF SERVICE

I do hearby certify that, on this 15th day of July, 2008, a true and correct copy of **Plaintiff, Elmer Heisner's, Individually, and on Behalf of Jayne Heisner, Amended Complaint** was served electronically upon the following individual:

Stephanie A. Scharf
Schoeman Updike Kaufman & Scharf
33 W. Wacker Dr., Suite 300
Chicago, IL 60606

By: /s/ Kurt D. Hyzy
Attorney for Plaintiff
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